

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A.,)	
INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 13-493 (SLR)
)	
AMNEAL PHARMACEUTICALS, LLC,)	
)	
Defendant.)	

**TAKEDA PHARMACEUTICALS U.S.A., INC.’S ANSWER
TO AMNEAL PHARMACEUTICALS, LLC’S COUNTERCLAIMS**

Plaintiff and Counterclaim Defendant Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”) hereby answers the counterclaims asserted by Defendant and Counterclaim Plaintiff Amneal Pharmaceuticals, LLC (“Amneal”) in the above-captioned case as follows:

COUNTERCLAIMS

108. Paragraph 108 contains a legal statement to which Takeda is not required to provide a response. To the extent a response is required, Takeda denies the allegations of Paragraph 108 and further denies that the patents-in-suit are invalid and/or not infringed.

PARTIES

109. Takeda is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 109 of the Counterclaims, and therefore denies them.

110. Admitted, except that One Takeda Parkway, Deerfield, Illinois 60015 is Takeda’s principal, not “principle”, place of business.

NATURE OF THE ACTION

111. Takeda admits that Amneal’s Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Takeda denies all the remaining allegations of

Paragraph 111. Takeda denies that Amneal is entitled to any of the requested relief and further denies that the patents-in-suit are invalid and/or not infringed.

JURISDICTION AND VENUE

112. Paragraph 112 contains legal conclusions to which Takeda is not required to provide a response. To the extent a response is required, Takeda does not contest that this Court has jurisdiction over the asserted counterclaims.

113. Paragraph 113 contains legal conclusions to which Takeda is not required to provide a response. To the extent a response is required, Takeda does not contest that venue is proper.

114. The allegations in Paragraph 114 of the Counterclaims contain legal conclusions and do not require a response. To the extent a response is required, Takeda admits that there is a justiciable controversy between the parties but denies the remaining allegations of Paragraph 114.

BACKGROUND

- 115. A. Admitted.
- B. Admitted.
- C. Admitted.
- D. Admitted.
- E. Admitted.
- F. Admitted.
- G. Admitted.
- H. Admitted.
- I. Admitted.

J. Admitted.

116. Takeda admits that it is the assignee and owner of the patents-in-suit and that it has all rights to enforce each patent-in-suit and to recover any fees, costs or damages awarded by the Court.

117. Admitted.

118. Admitted.

119. Takeda admits that it has properly listed patents on the Orange Book associated with NDA Numbers 22-351, 22-352, and 22-353 that claim, among other things, methods of using Colcrys to treat and/or prevent gout flares with or without concomitant administration of a second substance.

120. Takeda admits that it received from a representative of Counterclaim Plaintiff correspondence dated February 20, 2013, purporting to be a Paragraph IV certification letter. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 120 of the Counterclaims and therefore denies them.

121. Admitted.

122. Takeda admits that Amneal alleges that it does not infringe any patent-in-suit and/or that each patent-in-suit is invalid. Takeda denies that Amneal does not infringe its patents-in-suit and denies that any claim of any patent-in-suit is invalid. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 122 of the Counterclaims and therefore denies them.

123. Paragraph 123 contains legal conclusions to which Takeda is not required to provide a response. To the extent a response is required, Takeda admits that there is a real and actual controversy between Takeda and Amneal related to Amneal's filing of ANDA 20-4711.

FIRST COUNTERCLAIM

Declaratory Judgment of Non-Infringement of the Patents-in-Suit

124. Takeda incorporates its responses to Paragraphs 118-123 of the Counterclaim as if fully set forth herein.

125. Denied.

126. Denied.

127. Denied.

128. Denied.

129. Denied.

130. Denied.

131. Denied.

132. Denied.

133. Denied.

134. Denied.

SECOND COUNTERCLAIM

Declaratory Judgment of Invalidity of the Patents-in-Suit

135. Takeda incorporates its responses to Paragraphs 118-134 of the Counterclaim as if fully set forth herein.

136. Denied.

137. Denied.

138. Denied.

139. Denied.

140. Denied.

141. Denied.

142. Denied.

143. Denied.

144. Denied.

145. Denied.

THIRD COUNTERCLAIM

Delisting of the '004, '758, '681, '269, '648, '296, '297, and '655 Patents

146. Takeda incorporates its responses to Paragraphs 118-145 of the Counterclaim as if fully set forth herein.

147. Paragraph 147 contains legal conclusions to which Takeda is not required to provide a response. To the extent a response is required, Takeda denies the allegations in Paragraph 147.

148. Admitted.

149. Admitted.

150. Admitted.

151. Admitted.

152. Paragraph 152 contains legal conclusions to which Takeda is not required to provide a response. To the extent a response is required, Takeda admits that the '004, '758, '681, '269, '648, '296, '297, and '655 patents claim methods for the concomitant administration of colchicine and a drug other than colchicine.

153. Denied.

154. Denied.

155. Denied.

153. Denied.

157. Denied.

158. Denied.

159. Denied.

160. Denied.

161. Denied.

DEMAND FOR JUDGMENT

To the extent that this section may be deemed to allege any facts or any factual or legal entitlements to the relief requested, Takeda denies each and every such allegation. Specifically, Takeda, denies that any claim of any patent-in-suit is invalid and that any patent-in-suit is not infringed. Takeda additionally denies that Amneal is entitled to any of the requested relief.

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May 15, 2013
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/s/ Derek J. Fahnestock

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CERTIFICATE OF SERVICE

I hereby certify that on May 15, 2013, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on May 15, 2013, upon the following in the manner indicated:

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